

BUDD LARNER

A PROFESSIONAL CORPORATION
COUNSELLORS AT LAW

150 JOHN F. KENNEDY PARKWAY
SHORT HILLS, NJ 07078-2703
973.379.4800
FAX 973.379.7734
www.buddlerner.com

Direct Dial (973) 315-4439
E-Mail: apolack@buddlerner.com

July 10, 2013

Via ECF

The Honorable Joel A. Pisano
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, N.J. 08608

Re: *AstraZeneca/Pozen v. DRL, Lupin & Anchen*
Civil Action No. 3:11-CV-2317-JAP-DEA

Dear Judge Pisano:

We represent the DRL defendants and write to explain the connection between two letters recently sent to Judge Arpert concerning contentions (D.E. 147 & D.E. 151) and plaintiffs' motion for summary judgment filed June 28, 2013 (D.E. 152).¹ We ask that Your Honor schedule a telephone conference to address the matters discussed below and thereafter that Your Honor strike the summary judgment motion since there is no case or controversy or jurisdiction to hear it because it addresses a defense that DRL does not assert. A conference would be particularly helpful because the issues raised in the contention letters are now before Judge Arpert, but the summary judgment motion is before Your Honor. Nevertheless, because the contention letters and the summary judgment motion raise common issues, they should be assessed together.

These contention letters and this summary judgment motion relate to a contention dispute that arose last year. *See* D.E. 98, 116, 125, 127 - 129 and 134. In that dispute, Plaintiffs AstraZeneca and Pozen Inc. (collectively, "Pozen") sought leave to amend their responses to DRL's invalidity contentions. Pozen argued that the Court should grant Pozen leave to amend its responses to DRL's invalidity contentions because, *inter alia*, Lupin allowed Pozen to amend its

¹ We attach these contention letters here. They are unrelated to two other letters sent to Judge Arpert recently that concern claim construction (D.E. 148 & D.E. 150). The claim construction letters were forwarded to Your Honor under cover of John E. Flaherty's letter dated July 3, 2013 (D.E. 154).

Hon. Joel A. Pisano, U.S.D.J.
July 10, 2013
Page 2

responses to Lupin's invalidity contentions and Pozen wanted its contentions against DRL to be the same as its contentions against Lupin.

The DRL and Lupin actions are consolidated for discovery purposes. However, citing *Johnson v. Manhattan Ry. Co.*, 289 U.S. 479, 496-97 (1933), Judge Arpert denied Pozen's request because "consolidation is permitted as a matter of convenience and economy in administration, but does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." D.E. 134, p. 8. In short, Lupin's consent to let Pozen amend its contentions offered no basis to impose those contentions on DRL. Judge Arpert also rejected Pozen's other arguments for leave to amend its contentions. *Id.*, pp. 6 - 7.

After the parties briefed their contention dispute last year, but prior to the Court's decision regarding Pozen's contention amendment application (D.E. 134), Pozen sued DRL in a second Vimovo case (13-00091). Like the earlier Lupin (11-04275) and Anchen (11-06348) actions, the second DRL Vimovo case is also consolidated for discovery purposes with the first DRL Vimovo case (11-02317). However, DRL's proposed ANDA product in the second DRL Vimovo case is different from its proposed ANDA product in the first DRL Vimovo case. DRL developed a different formulation for its second Vimovo ANDA specifically designed to avoid, and therefore not infringe, the claims of the '907 patent.

Based upon that difference, Judge Arpert had DRL and Pozen exchange new contentions pursuant to the Local Patent Rules. *See* D.E. 145. Pursuant to that Order and the Local Patent Rules, Pozen identified the claims of the '907 patent it believed DRL's second Vimovo ANDA infringed. DRL responded only with non-infringement contentions, because unlike in the first DRL Vimovo case, in the second DRL Vimovo case, DRL had no need to reach the issue of invalidity because non-infringement offers it a complete defense. Thus, DRL served no invalidity contentions in the second DRL Vimovo case.

Despite the absence of invalidity contentions in the second DRL Vimovo case, Pozen submitted "validity contentions." When asked why it submitted validity contentions when DRL served no invalidity contentions, Pozen said that its validity contentions responded to DRL's invalidity contentions in the first DRL Vimovo action and DRL's three-line affirmative defense of invalidity in its second DRL Vimovo case answer. The parties discussed this issue with Judge Arpert during a June 21, 2013 status conference. He directed the parties to write letters explaining this issue further. That request led to the letters attached here (D.E. 147, D.E. 151) as well as Pozen's summary judgment motion. Since the letters and motion both concern the absence of DRL invalidity contentions, both should be addressed together and by the same judge.

Hon. Joel A. Pisano, U.S.D.J.

July 10, 2013

Page 3

Pozen's contention letter to Judge Arpert (D.E. 151, p. 2) explains that it seeks summary judgment of validity in the second DRL Vimovo case to preclude DRL from litigating invalidity in the first DRL Vimovo case. Recognizing that it would need to prove that "invalidity" was "actually litigated" in the second DRL Vimovo case in order to achieve the preclusive effect it seeks,² Pozen cites the *Restatement (Second) of Judgments* § 27 (1980), and specifically comment (d). Specifically, Pozen argues:

Summary judgment on the issue of validity in this case will preclude DRL from litigating the same issue in DRL I. "When an issue of fact or law is actually litigated¹ and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties,² whether on the same or a different claim." *Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n*, 288 F.3d 519, 525 (3rd Cir. 2002) (quoting *Restatement (Second) of Judgments* § 27 (1980)).

¹"When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination, and is determined, the issue is actually litigated within the meaning of this Section. An issue may be submitted and determined on . . . a motion for summary judgment. . . . A determination may be based on a failure of . . . proof." *Restatement (Second) of Judgments* § 27 cmt. D (1980).

²"If two actions which involve the same issue are pending between the same parties, it is the first final judgment rendered in one of the actions which becomes conclusive in the other action, regardless of which action was brought first." *Restatement (Second) of Judgments* § 27 cmt. 1 (1980)); *see also id.* § 14 ("For purposes of res judicata, the effective date of a final judgment is the date of its rendition, without regard to the date of commencement of the action in which it is rendered or the action in which it is to be given effect.")

However, this same *Restatement*, in the very next comment, clearly explains why Pozen's 3-page summary judgment motion cannot yield an "actually litigated" result.

Comment (e) of this *Restatement*, entitled "*Issues not actually litigated*," explains that:

- "There are many reasons why a party may choose not to raise an issue, or to contest an assertion, in a particular action." (*Here, for example, DRL has no need to argue invalidity in its second case and, in fact, if it succeeds in its non-infringement argument will benefit from not invalidating the patent.*)

² As the party contending that an issue has been conclusively litigated and determined in a prior action, Pozen has the burden of proving this contention. *See Restatement (Second) of Judgments* § 27 (1980), cmt. (f).

Hon. Joel A. Pisano, U.S.D.J.

July 10, 2013

Page 4

- “[I]f preclusive effect were given to issues not litigated, the result might serve to discourage compromise, to decrease the likelihood that the issues in an action would be narrowed by stipulation and thus intensify litigation.” (*Here, for example, DRL would not choose to narrow the issues in the second DRL Vimovo case by dropping a validity challenge if the effect of that required DRL to concede validity in the first DRL Vimovo case.*)
- “An issue is not actually litigated if the defendant might have interposed it as an affirmative defense but failed to do so; nor is it actually litigated if it is raised by a material allegation of a party’s pleading but is admitted (explicitly or by virtue of a failure to deny) in a responsive pleading.” (*Here, the issue would not be litigated because DRL’s failure to raise it in contentions would be an admission of or a failure to deny validity.*)
- “In the case of a judgment entered by confession, consent, or default, none of the issues is actually litigated. Therefore, the rule of this Section does not apply with respect to any issue in a subsequent action.” (*Here, because Pozen’s summary judgment motion would be equivalent to a default judgment, it cannot be “actually litigated.”*)

Courts in the Third Circuit and elsewhere have held that matters were not “actually litigated” in situations like this one. *See Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 763 F. Supp. 2d 671, 680 (D. Del. 2010) (Where the same parties in a prior trial litigated patent obviousness (after the accused infringer generally pled patent invalidity in its answer), issue preclusion did not apply to anticipation in a second trial regarding the same patent and the same parties because anticipation was not “actually litigated” though obviousness was). If the assertion of invalidity in general in an answer,³ plus subsequent litigation through trial of obviousness cannot preclude later litigation of anticipation of the same patent, DRL’s dropping its affirmative defense of all invalidity issues cannot preclude all invalidity contentions in a separate case. Moreover, where an issue is not argued by a party and thus receives insufficient analysis by the Court, that issue is not “actually litigated” and cannot have preclusive effect in a later case. *See Chicago Truckers Drivers Pension Fund v. Century Motor Freight, Inc.*, 125 F.3d 526, 530 (7th Cir. 1997).⁴

³ The *Power* decision does not describe the affirmative defenses to the complaint at issue. However, that answer included a general invalidity defense. *See Power*, No. 08-309, D.E. 49, ¶ 30 (D. Del. filed Nov. 7, 2008), “Second Defense: Invalidity of the Asserted Patents” (“The ‘851 Patent, the ‘876 Patent, and the ‘270 Patent are invalid for failing to comply with the provisions of the Patent Laws, Title 35 U.S.C, including without limitation 35 U.S.C §§ 102, 103, 112, 121 and/or under the doctrine of obviousness-type double patenting”).

⁴ Courts have also held that an issue is not “actually litigated” if a party drops its defense relevant to it. *See Amadeo v. Principal Mutual Life Ins. Co.*, 290 F.3d 1152, 1159 (9th Cir. 2002) (“A voluntary dismissal of a claim prior any adjudication and without any stipulated findings of fact does not actually litigate any issue”); *Adolph Coors Co. v.*

Hon. Joel A. Pisano, U.S.D.J.
 July 10, 2013
 Page 5

Both this Court's Local Patent Rules and the law regarding issue preclusion work to streamline litigation and focus the parties on the core issues and resolve others. *See* D.E. 134, p. 4. ("The rules are designed specifically to 'require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed.'" *citing Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998). *Restatement (Second) of Judgments* § 27 (1980), comment (e) ("[I]f preclusive effect were given to issues not litigated, the result might serve to discourage compromise, to decrease the likelihood that the issues in an action would be narrowed by stipulation and thus intensify litigation").

The Local Patent Rules narrow cases by requiring an identification of asserted claims. The point of doing that before disclosure of non-infringement and/or invalidity contentions is so that those contentions address only the asserted claims. *See* Allyn Lite, New Jersey Federal Practice Rules (2013 ed.), Comment to Local Civil Rule 9.3, at 151. Similarly, *responsive* contentions properly address only those already raised. By attempting to conflate the contentions in the two DRL Vimovo cases, Pozen upends a primary purpose of the Local Patent Rules: to streamline cases and remove issues. Rather than focusing on DRL's existing non-infringement contentions in the second DRL Vimovo case, Pozen proposes to add in new "validity contentions" to a case with no invalidity contentions. In doing so, Pozen seeks to broaden what should be a relatively straightforward non-infringement case by forcing DRL to assert invalidity in the second case or to risk preclusion in the first case based on a procedurally defective summary judgment motion. We ask Your Honor to strike Pozen's motion for lack of subject matter jurisdiction.

The case law in this jurisdiction holds that such motion practice is forbidden. Based on a lack of the requisite "case and controversy," Judge Garrett Brown procedurally denied summary judgment of invalidity of a claim in a patent case because of a patent holder's statement that it would not assert that claim against the accused infringer in that or any other case. *See Teva Pharm. Ind., Ltd. v. Dr. Reddy's Lab., Ltd.*, 2008 U.S. Dist. LEXIS 16958 at *11 (D.N.J. Mar. 4, 2008) ("The case and controversy requirement must be evaluated claim by claim. . . and Teva has conceded that it is not pursuing an infringement claim as to claim 1 of the '008 patent").

IRS, 519 F.2d 1280, 1283 (10th Cir. 1975) ("To obtain the protection afforded by the doctrine of collateral estoppel an issue must have been raised, litigated and actually adjudged on the merits in the first proceeding. Here, the overhead issue was raised but, because it was abandoned by the IRS, was not judicially determined"); *U.S. v. Young*, 804 F.2d 116, 118 (8th Cir. 1986) ("A fact established in prior litigation not by judicial resolution but by stipulation has not been 'actually litigated' and thus is the proper subject of proof in subsequent proceedings"); *Serby v. First Alert, Inc.*, 2013 U.S. Dist. LEXIS 45942, at *15 (E.D.N.Y. Mar. 27, 2013), *citing Restatement (Second) of Judgments* § 27, comment (e) (earlier settlement and Rule 41 dismissal with prejudice had no preclusive effect in later patent case concerning same patent because "[w]here a judgment between parties is entered by consent prior to trial on any issue, no issue may be said to have been fully, fairly or actually litigated").

942029v2


Hon. Joel A. Pisano, U.S.D.J.
July 10, 2013
Page 6

Moreover, when pursuant to this Court's Local Patent Rules, a party narrows its asserted claims in contentions, the Court loses subject matter jurisdiction over those not asserted in the contentions, even if they had been asserted in the complaint. *See Hoffman-La Roche Inc. v. Mylan Pharm. Inc.*, 2009 U.S. Dist. LEXIS 114784 at *20–21 (D.N.J. Dec. 9, 2009) (accused infringer failed to demonstrate a live case or controversy with respect to claims whose assertion patent holder did not carry forward in local rule contentions).

Here, like the patentees in the case above who dropped their assertion of particular patent claims, DRL has dropped the affirmative defense of invalidity through its contentions. Thus, there is no case and controversy regarding invalidity in the second DRL Vimovo case and the Court should strike Pozen's summary judgment motion without requiring a DRL response. That would properly keep the issues narrowly focused on the only dispute, *i.e.*, non-infringement. The alternative (which Pozen hopes to provoke) is for DRL to seek amendment of its contentions to raise invalidity in the second case or to litigate in the first case whether the grant of summary judgment in case two has preclusive effect in case one.

Since we believe Pozen's motion is improper, and hope to avoid unnecessary motion practice, we ask for a conference on this issue and, after such submissions and consideration as Your Honor deems appropriate, that Your Honor strike the motion.

Respectfully submitted,


Alan H. Pollack

cc: Counsel of Record (by email)

BUDD LARNER

A PROFESSIONAL CORPORATION
COUNSELLORS AT LAW

150 JOHN F. KENNEDY PARKWAY
SHORT HILLS, NJ 07078-2703
973.379.4800
FAX 973.379.7734
www.buddlerner.com

Direct Dial (973) 315-4439
E-Mail: apollack@buddlerner.com

June 26, 2013

Via ECF

The Honorable Douglas E. Arpert
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, N.J. 08608

Re: *AstraZeneca/Pozen v. DRL, Lupin & Anchen*
Civil Action No. 3:11-CV-2317-JAP-DEA

Dear Judge Arpert:

As per Your Honor's instructions during the June 21, 2013 scheduling conference, DRL writes to explain why the "validity contentions" sent by Pozen on June 13, 2013 are improper and contravene this Court's Local Patent Rules. The Local Patent Rules permit a "response to invalidity contentions" when the accused infringer serves invalidity contentions. In the case at issue, DRL served no invalidity contentions. Pozen's "response" is therefore improper and should be stricken.

At the May 9, 2013 status conference, Pozen argued that its second vimovo case against DRL needed a new and discrete round of contentions under the Local Patent Rules. Accordingly, the Court entered a Scheduling Order (D.E. 145) specific to the second of the two DRL vimovo cases that required "DRL [to] disclose its invalidity and non-infringement contentions to Plaintiffs by May 23, 2013." *DRL disclosed only non-infringement contentions and disclosed no invalidity contentions.* As a result, unless DRL were to seek leave to amend its contentions, it cannot in this case argue invalidity – even if its Notice Letter raised that possibility. But unlike the ANDA product at issue in the first DRL vimovo case, DRL designed the ANDA product at issue here specifically to avoid infringement, and therefore this case does not need to reach the issue of invalidity. Accordingly, DRL did not serve invalidity contentions. Pozen nevertheless interposed validity contentions *despite DRL's decision to forgo any invalidity contentions.*

00940788

NEW YORK

CHERRY HILL

SHORT HILLS

PHILADELPHIA

Hon. Douglas E. Arpert, U.S.M.J.

June 26, 2013

Page 2

During the June 21st telephone conference, Stephen Hash, on behalf of Pozen, argued that Pozen had a “duty and obligation” to submit “validity contentions” because DRL’s answer and Notice Letter referenced invalidity defenses. That is the only argument Pozen offers. That argument must fail because it renders L. Pat. R. 3.6(c) meaningless and undermines the main point of the contention process of the Local Patent Rules: to winnow the issues down and focus the case on fewer disputes. Surely Pozen does not contend that DRL, who failed to serve invalidity contentions, can nevertheless argue invalidity because its Notice Letter discussed invalidity. To the contrary, DRL would be required to seek leave of court to add invalidity contentions belatedly. If the Court were to permit belated invalidity contentions, the Court would then permit the patent holder to put in a “Response to Invalidity Contentions.” *See* L. Pat. R. 3.6(i). But an amendment to add invalidity contentions is not a matter of right. As Your Honor has held in several cases including this one, “the Local Patent Rules require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed,” *King Pharms., Inc. v. Sandoz Inc.*, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). D.E. 134, p. 9.

Pozen’s stated excuse – “needing” to respond to DRL’s answer and Notice Letter – is therefore plainly untrue. What Pozen is apparently trying to do is to use the contention process of the second DRL *vimovo* case as a hook to refer to and use in the first DRL *vimovo* case the very contentions this Court refused Pozen leave to add into the first DRL *vimovo* case. *See* D.E. 134. But slipping those contentions into the second DRL *vimovo* case is inappropriate.¹ As this Court noted just three months ago in denying Pozen leave to amend contentions in the first DRL *vimovo* case, consolidation for discovery does not merge the various cases. D.E. 134, p. 8 (“Plaintiffs, therefore, may not amend their responses simply to promote uniformity among the consolidated actions.”).

If Pozen thinks the existence of the second DRL *vimovo* case justifies an amendment to its contentions in the first DRL *vimovo* case, it should be forthright and say so. Then the proper path for Pozen would be to seek leave to amend its contentions in the first DRL *vimovo* case and not to pretend that assertions made in the Notice Letter or a three-line affirmative defense in an answer, *but that DRL never carried forward in any contentions*, somehow warrant Pozen’s 60-page “validity contention” response. If Pozen were to make such a motion, DRL could then respond to whatever arguments Pozen may make and the Court would have the merits of the issue presented.

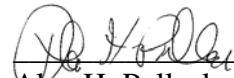
¹ Incorporating the disputed validity contentions into the second DRL *vimovo* case is also pointless since DRL does not in the second DRL *vimovo* case claim the patent is invalid.

Hon. Douglas E. Arpert, U.S.M.J.
June 26, 2013
Page 3

There are seven prior versions of Pozen “validity contentions.”² This would be the eighth, and the fourth directed to DRL. Pozen’s effort to introduce yet another set of “validity contentions” through the back door must be rejected.

For all the reasons set forth here and in the D.E. 116, 129 and 134, the Court should strike Pozen’s June 14, 2013 “validity contentions” in their entirety. DRL encloses a Proposed Order for the convenience of the Court consistent with this request.

Respectfully submitted,


Alan H. Pollack

cc: Counsel of Record (by email)
attachment

² (1) Pozen’s original validity contentions to DRL; (2) Pozen’s original validity contentions to Lupin; (3) Pozen’s Proposed Amended validity contentions to Lupin; (4) Pozen’s Proposed Amended validity contentions to DRL; (5) Pozen’s “Compromise” validity contentions to Lupin; (6) Pozen’s proposed “Compromise” validity contentions to DRL; and (7) Pozen’s validity contentions to Anchen.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC.,	:	Civil Action No. 11-2317 (JAP-DEA)
Plaintiffs,	:	
v,	:	
DR. REDDY’S LABORATORIES INC. and: DR. REDDY’S LABORATORIES LTD.,	:	
Defendants.	:	
ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC.,	:	Civil Action No. 11-04275 (JAP-DEA)
Plaintiffs,	:	
v.	:	
LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,	:	
Defendants.	:	
ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN INC.,	:	Civil Action No. 11-06348 (JAP-DEA)
Plaintiffs,	:	
v.	:	
ANCHEN PHARMACEUTICALS, INC.,	:	
Defendants.	:	
ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC.,	:	Civil Action No. 13-00091 (JAP)(DEA)
Plaintiffs,	:	
v,	:	
DR. REDDY’S LABORATORIES INC. and: DR. REDDY’S LABORATORIES LTD.,	:	
Defendants.	:	

[PROPOSED] ORDER STRIKING CONTENTIONS

WHEREAS, Defendants Dr. Reddy’s Laboratories Inc. and Dr. Reddy’s Laboratories Ltd. (“DRL”) has, by letter dated June 26, 2013, moved to strike the contentions of Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc. (“Pozen”), entitled “ASTRAZENECA AB’S, ASTRAZENECA LP’S, KBI-E INC.’S, AND POZEN INC.’S RESPONSES TO DR. REDDY’S LABORATORIES, INC. AND DR. REDDY’S LABORATORIES, LTD.’S INVALIDITY CONTENTIONS PURSUANT TO L. PAT. R. 3.6(i)” and the associated chart entitled “PLAINTIFFS’ RESPONSIVE

CONTENTIONS PURSUANT TO L. PAT. R. 3.4A(c) and 3.6(i),” both dated June 13, 2013;

WHEREAS, by letter dated June 28, 2013, Pozen opposed DRL’s motion to strike the Pozen contentions described above;

THEREFORE, these matters, having come before the Court in the status conference conducted on June 21, 2013, and all parties having had a full opportunity to be heard through the letters described above:

IT IS on this ____th day of July, 2013,

ORDERED that the motion to strike the invalidity contentions described above is **GRANTED**.

DOUGLAS E. ARPERT
United States Magistrate Judge



June 28, 2013

VIA ECF

Hon. Douglas E. Arpert, U.S.M.J.
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

**RE: *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*,
Civ. Action No. 3:11-cv-02317 (consolidated for discovery)**

John E. Flaherty
Partner
T. 973.639.7903
F. 973.297.3971
jflaherty@mccarter.com

McCarter & English, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102-4056
T. 973.622.4444
F. 973.624.7070
www.mccarter.com

Dear Judge Arpert:

We, along with Covington & Burling and Vinson & Elkins represent Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs") in this Hatch-Waxman litigation involving the patents related to the product Vimovo[®]. DRL has filed two separate ANDAs relating to those patents. Those filings came nearly two years apart and have resulted in two separate Hatch-Waxman cases. Civil Case No. 3:11-cv-2317 ("DRL I") was filed on April 21, 2011. Civil Case No. 3:13-cv-91 ("DRL II") is more recent, filed on January 4, 2013.

This letter responds to DRL's June 26, 2013, letter in which DRL challenged Plaintiffs' service of Responses to Invalidity Contentions in DRL II under L. Pat. R. 3.4A and 3.6(i) (the "Responses"). In their letter, DRL suggests entry of an order striking Plaintiffs' Responses. In this letter, we suggest the entry of an order granting summary judgment against DRL on its affirmative defense of patent invalidity.

Plaintiffs served their Responses to rebut DRL's allegations that the claims of U.S. Pat. No. 6,929,907 ("the '907 Patent") are invalid. DRL certified to the FDA that the claims of the '907 Patent were, *inter alia*, invalid in connection with its second ANDA, and detailed its invalidity allegations in its November 20, 2012, Notice Letter to Plaintiffs. Plaintiffs, in their Complaint, requested that the Court resolve that dispute by entering judgment that the claims of the patents-in-suit, including the '907 Patent, are valid. See Dkt. 1. DRL, in turn, pleaded invalidity of the '907 Patent as an affirmative defense in its Answer.

Despite the dispute over the validity of the '907 Patent, DRL did not serve invalidity contentions to support its defense or to rebut Plaintiffs' request for judgment. DRL provided no explanation at the time for its failure to do so.

BOSTON

HARTFORD

NEW YORK

NEWARK

PHILADELPHIA

STAMFORD

WILMINGTON

Hon. Douglas E. Arpert, U.S.M.J.
 June 28, 2013
 Page 2

Plaintiffs served their Responses to rebut DRL's allegations of invalidity "to the extent DRL intends to rely on or incorporate by reference its Invalidity Contentions served in DRL I in this case." Responses at 1. Shortly after Plaintiffs served their responses, DRL informed Plaintiffs that DRL had decided not to serve invalidity contentions in this case, and DRL's letter to the Court likewise states that it has made a "decision to forgo any invalidity contentions" in this case.

If DRL's adamant representation that it has decided not to put forward evidence of invalidity in this case can be taken at face value, the Court should enter summary judgment in Plaintiffs' favor on DRL's affirmative defense of invalidity. Patent claims are presumed valid and may only be proven invalid by clear and convincing evidence. *Robotic Visions Sys., v. View Eng'g., Inc.*, 189 F.3d 1370, 1377 (Fed. Cir. 1999). Without any evidence to support its affirmative defense of invalidity, DRL cannot prevail on that defense, and Plaintiffs are entitled to summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 477-78 (1986) ("One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses."). Accordingly, Plaintiffs are filing today and providing with this letter a motion for summary judgment that the claims of the '907 Patent are not invalid.

Summary judgment on the issue of validity in this case will preclude DRL from litigating the same issue in DRL I. "When an issue of fact or law is actually litigated¹ and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties,² whether on the same or a different claim." *Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n*, 288 F.3d 519, 525 (3rd Cir. 2002) (quoting Restatement (Second) of Judgments § 27 (1980)).

It may be that DRL wants to be taken at its word that it does not contest the validity of the patent and, presumably, is prepared to have judgment entered. That judgment may moot the entire issue in both cases.

¹ "When an issue is properly raised, by the pleadings or otherwise, and is submitted for determination, and is determined, the issue is actually litigated within the meaning of this Section. An issue may be submitted and determined on . . . a motion for summary judgment A determination may be based on a failure of . . . proof." Restatement (Second) of Judgments § 27 cmt. D (1980).

² "If two actions which involve the same issue are pending between the same parties, it is the first final judgment rendered in one of the actions which becomes conclusive in the other action, regardless of which action was brought first." Restatement (Second) of Judgments § 27 cmt. 1 (1980)); *see also id.* § 14 ("For purposes of res judicata, the effective date of a final judgment is the date of its rendition, without regard to the date of commencement of the action in which it is rendered or the action in which it is to be given effect.")

Hon. Douglas E. Arpert, U.S.M.J.
June 28, 2013
Page 3

Now, it may be that DRL decided to try for some strategic or tactical advantage in the DRL II case by not raising invalidity contentions. Rather, mindful that Your Honor had denied Plaintiffs' request to amend its Responses to DRL's invalidity contentions in the earlier DRL I case, the defendant may have hoped to prevent Plaintiffs from presenting the full response in DRL II: a case that came about because DRL elected to file a second ANDA challenging the same patents. It was DRL's decision that resulted in the second case (DRL II). If DRL is not willing to consent to judgment on validity it should not be allowed to preclude a full defense of the validity of the patents in both cases.

If DRL is seeking some strategic advantage by, in effect, relying on its DRL I invalidity contentions and invalidity defense for the DRL II case without giving Plaintiffs an opportunity to provide the responses to those contentions—as required under the Court's Local Rules—then Plaintiffs should have an opportunity to provide their Responses. DRL chose to file a second ANDA and chose to raise the issue of validity in the ensuing case, aware that these choices would lead to an opportunity, not only for itself to raise new invalidity contentions or rely on those served in DRL I, but also for Plaintiffs to respond.

Perhaps recognizing this issue, on page 2 of its letter, DRL recognizes that the second action represents changed conditions and arguably would warrant application of the Responses to both cases. We agree. The filing of the second case following from DRL's decision to file a second ANDA is a changed circumstance that provides good cause for amending the Responses in DRL I. Plaintiffs have timely provided their Responses, and DRL cannot now argue that it will be prejudiced by alleged delay in Plaintiffs' Responses as it did in its opposition to Plaintiff's earlier motion for leave to amend in DRL I. The new case is just getting underway, and the parties have now largely agreed to a schedule to start and finish fact and expert discovery. The Responses in DRL II should stand and Amendment in DRL I is appropriate under all the present circumstances.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty

cc: Counsel of Record (via email)